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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

DANIEL SILVER, et. al.,
Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE, LLC,
Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-5704-CRB

) **PFIZER INC., PHARMACIA
CORPORATION, AND G.D.
SEARLE, LLC'S ANSWER TO
COMPLAINT**

) **JURY DEMAND ENDORSED
HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
 3 (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively
 4 "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would
 5 respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used
 9 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
 10 Defendants may seek leave to amend this Answer when discovery reveals the specific time
 11 periods in which Plaintiffs were prescribed and used Bextra®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but
 16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
 17 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
 18 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
 19 accordance with their approval by the FDA. Defendants admit that, during certain periods of
 20 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
 21 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
 22 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 23 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
 24 with its FDA-approved prescribing information. Defendants state that the potential effects of
 25 Bextra® were and are adequately described in its FDA-approved prescribing information,
 26 which was at all times adequate and comported with applicable standards of care and law.
 27 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,
 28 and deny the remaining allegations in this paragraph of the Complaint.

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2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Bextra® in the United States, including the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore,

1 deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

2 **Response to Allegations Regarding Jurisdiction and Venue**

3 6. Defendants are without knowledge or information to form a belief as to the truth of the
4 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
5 therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount
6 in controversy exceeds \$75,000, exclusive of interests and costs.

7 7. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship, and,
9 therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are
10 diverse. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 8. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
13 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny
14 committing a tort in the States of California, Ohio, South Carolina, Florida, Illinois,
15 Washington, Michigan, Arizona, Texas, and Maryland, and deny the remaining allegations in
16 this paragraph of the Complaint.

17 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Bextra® in the United States, including the States of California, Ohio, South
19 Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be
20 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
21 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
22 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
23 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that they provided FDA-approved prescribing information regarding Bextra®.
26 Defendants admit that they do business in the State of Texas. Defendants state that Plaintiffs'
27 allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are
28 without knowledge or information to form a belief as to the truth of such allegations, and,

1 therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining
2 allegations in this paragraph of the Complaint.

3 **Response to Allegations Regarding Interdistrict Assignment**

4 10. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendants
6 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
7 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
8 Panel on Multidistrict Litigation on September 6, 2005.

9 **Response to Factual Allegations**

10 11. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
12 Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused
13 Plaintiff injury or damage and deny the remaining allegations in this paragraph of the
14 Complaint.

15 12. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
17 Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused
18 Plaintiff injury or damage and deny the remaining allegations in this paragraph of the
19 Complaint.

20 13. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
22 Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused
23 Plaintiff injury or damage and deny the remaining allegations in this paragraph of the
24 Complaint.

25 14. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
27 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
28 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 15. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
4 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
5 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
6 paragraph of the Complaint.

7 16. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
9 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
10 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
11 paragraph of the Complaint.

12 17. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
14 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
15 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
16 paragraph of the Complaint.

17 18. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
19 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
20 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
21 paragraph of the Complaint.

22 19. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether
24 Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct,
25 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
26 paragraph of the Complaint.

27 20. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the

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1 same. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 21. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
9 same. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
14 the Complaint.

15 22. Defendants admit that Bextra® was expected to reach consumers without substantial
16 change from the time of sale. Defendants are without knowledge or information sufficient to
17 form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and,
18 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the
19 Complaint.

20 23. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants are without knowledge or information sufficient to form a belief as to the truth of
25 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.
26 Defendants deny remaining the allegations in this paragraph of the Complaint.

27 24. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the

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1 same. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,
6 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

7 25. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
8 damage, and deny the remaining allegations in this paragraph of the Complaint, including all
9 subparts.

10 26. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
11 steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that Bextra® was and is safe
12 and effective when used in accordance with its FDA-approved prescribing information.
13 Defendants state that the potential effects of Bextra® were and are adequately described in its
14 FDA-approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 27. The allegations in this paragraph of the Complaint are not directed toward Defendants
18 and, therefore, no response is required. To the extent a response is deemed required,
19 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
20 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
21 form a belief as to the truth of such allegations and, therefore, deny the same.

22 28. The allegations in this paragraph of the Complaint are not directed toward Defendants
23 and, therefore, no response is required. To the extent a response is deemed required,
24 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
25 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
26 form a belief as to the truth of such allegations and, therefore, deny the same.

27 29. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
28 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth

1 of such allegations and, therefore, deny the same.

2 30. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are
3 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
4 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
5 conduct and deny the remaining allegations in this paragraph of the Complaint.

6 31. Plaintiffs do not allege having used Celebrex® in this Complaint. Nevertheless,
7 Defendants admit that Celebrex® was launched in the United States in February 1999.
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
10 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
11 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
12 with their approval by the FDA. Defendants admit that, during certain periods of time,
13 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
14 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
15 providers who are by law authorized to prescribe drugs in accordance with their approval by the
16 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
17 directed toward Defendants and, therefore, no response is required. To the extent a response is
18 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
19 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
20 therefore lack sufficient information or knowledge to form a belief as to the truth of such
21 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
22 paragraph of the Complaint.

23 32. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
24 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
25 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
26 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
27 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
28 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of

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1 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
2 this paragraph of the Complaint.

3 33. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
4 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
5 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
6 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 34. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
9 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
10 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
11 the remaining allegations in this paragraph of the Complaint.

12 35. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
13 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
14 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
15 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
16 prescribing information. Defendants state that the potential effects of Bextra® were and are
17 adequately described in its FDA-approved prescribing information, which at all times was
18 adequate and comported with applicable standards of care and law. Defendants deny the
19 remaining allegations in this paragraph of the Complaint.

20 36. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which at all times was adequate and comported with applicable standards of care and law.
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
25 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
26 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
27 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
28 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be

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1 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
2 with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding
3 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
4 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 37. Defendants state that the referenced article speaks for itself and respectfully refer the
8 Court to the article for its actual language and text. Any attempt to characterize the article is
9 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
11 this paragraph of the Complaint.

12 38. The allegations in this paragraph of the Complaint are not directed towards Defendants
13 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
14 state that the referenced article speaks for itself and respectfully refer the Court to the article for
15 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
16 the remaining allegations in this paragraph of the Complaint.

17 39. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
18 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
19 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
20 paragraph of the Complaint.

21 40. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which at all times was adequate and comported with applicable standards of care and law.
25 Defendants deny the allegations in this paragraph of the Complaint.

26 41. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants deny the allegations in this
28 paragraph of the Complaint.

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1 42. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
2 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
3 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 43. Defendants state that the referenced article speaks for itself and respectfully refer the
6 Court to the article for its actual language and text. Any attempt to characterize the article is
7 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 44. Plaintiffs fail to provide the proper context for the allegations concerning the “post-drug
9 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without
10 sufficient information to confirm or deny such allegations and, therefore, deny the same.
11 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
12 the study for its actual language and text. Any attempt to characterize the study is denied.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 45. The allegations in this paragraph of the Complaint are not directed towards Defendants
15 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
16 state that the referenced article speaks for itself and respectfully refer the Court to the article for
17 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
18 the remaining allegations in this paragraph of the Complaint.

19 46. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
21 deny the remaining allegations in this paragraph of the Complaint.

22 47. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
23 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
24 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 48. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
27 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
28 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 49. Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 50. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
7 this paragraph of the Complaint.

8 51. Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 52. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 53. Defendants state that the referenced articles speak for themselves and respectfully refer
15 the Court to the articles for their actual language and text. Any attempt to characterize the
16 articles is denied. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 54. Defendants state that the referenced article speaks for itself and respectfully refer the
19 Court to the article for its actual language and text. Any attempt to characterize the article is
20 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 55. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants deny the allegations in this
23 paragraph of the Complaint.

24 56. Defendants state that the referenced article speaks for itself and respectfully refer the
25 Court to the article for its actual language and text. Any attempt to characterize the article is
26 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
27 paragraph of the Complaint.

28 57. The allegations in this paragraph of the Complaint are not directed towards Defendants

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1 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
2 state that the referenced article speaks for itself and respectfully refer the Court to the article for
3 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
4 the remaining allegations in this paragraph of the Complaint.

5 58. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny the allegations in this paragraph of the Complaint.

10 59. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
15 allegations in this paragraph of the Complaint.

16 60. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 61. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
26 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
27 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
28 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Bextra® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants are without knowledge or information
5 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used
6 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
7 allegations in this paragraph of the Complaint.

8 62. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed
9 toward Defendants and, therefore, no response is required. To the extent a response is deemed
10 required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in
11 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient
12 information or knowledge to form a belief as to the truth of such allegations and, therefore,
13 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in
14 this paragraph of the Complaint.

15 63. Defendants state that the referenced article speaks for itself and respectfully refer the
16 Court to the article for its actual language and text. Any attempt to characterize the article is
17 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 64. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
20 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
21 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
22 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
23 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
24 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
25 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Bextra® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny the remaining allegations in this
2 paragraph of the Complaint.

3 65. Defendants state that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
8 deny the remaining allegations in this paragraph of the Complaint.

9 66. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
10 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state
11 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its
12 actual language and text. Any attempt to characterize the letter is denied. Defendants admit
13 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the
14 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual
15 language and text. Any attempt to characterize the letter is denied. Defendants state that the
16 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and
17 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to
18 characterize the transcripts is denied. Defendants state that the referenced study speaks for
19 itself and respectfully refer the Court to the article for its actual language and text. Any attempt
20 to characterize the article is denied. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 67. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
23 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
24 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
25 that the referenced press release speaks for itself and respectfully refer the Court to the press
26 release for its actual language and text. Any attempt to characterize the press release is denied.
27 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
28 the article for its actual language and text. Any attempt to characterize the article is denied.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 68. Defendants state that the referenced press release speaks for itself and respectfully refer
4 the Court to the press release for its actual language and text. Any attempt to characterize the
5 press release is denied. Defendants deny any wrongful conduct and deny the remaining
6 allegations in this paragraph of the Complaint.

7 69. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Bextra® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants admit, as indicated in the package insert
18 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
19 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
20 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 70. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which at all times was adequate and comported with applicable standards of care and law.
25 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
26 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
27 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
28 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

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71. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 75. Defendants deny the allegations in this paragraph of the Complaint.

3 76. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
5 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
7 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
8 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
9 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Bextra® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
14 remaining allegations in this paragraph of the Complaint.

15 77. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the
17 same. Defendants state that the referenced press releases speak for themselves and respectfully
18 refer the Court to the press releases for their actual language and text. Any attempt to
19 characterize the press releases is denied. Defendants state that Bextra® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Bextra® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 78. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the
27 same. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,
4 and deny the remaining allegations in this paragraph of the Complaint.

5 79. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
10 allegations in this paragraph of the Complaint.

11 80. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 81. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 82. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
24 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
26 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
27 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

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1 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 83. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
5 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
7 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
8 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
9 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 **Response to First Cause of Action: Negligence**

12 84. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
13 Complaint as if fully set forth herein.

14 85. Defendants state that this paragraph of the Complaint contains legal contentions to
15 which no response is deemed required. To the extent a response is deemed required,
16 Defendants admit that they had duties as are imposed by law but deny having breached such
17 duties. Defendants state that the potential effects of Bextra® were and are adequately described
18 in its FDA-approved prescribing information, which was at all times adequate and comported
19 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 deny the remaining allegations in this paragraph of the Complaint.

22 86. Defendants state that this paragraph of the Complaint contains legal contentions to
23 which no response is deemed required. To the extent a response is deemed required,
24 Defendants admit that they had duties as are imposed by law but deny having breached such
25 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 87. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is required. To the extent that a response is deemed required, Defendants
2 admit that they had duties as are imposed by law but deny having breached such duties.
3 Defendants state that Bextra® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
8 including all subparts.

9 88. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants are without knowledge or information sufficient to form a belief as to the truth of
14 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 89. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 90. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
25 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this
26 paragraph of the Complaint.

27 91. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 92. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed
6 toward Defendants and, therefore, no response is required. To the extent a response is deemed
7 required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in
8 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient
9 information or knowledge to form a belief as to the truth of such allegations and, therefore,
10 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in
11 this paragraph of the Complaint.

12 93. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 94. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 95. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
19 damage and deny the remaining allegations in this paragraph of the Complaint.

20 96. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Second Cause of Action: Strict Liability**

23 97. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
24 Complaint as if fully set forth herein.

25 98. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
27 same. Defendants admit that Bextra® was expected to reach consumers without substantial
28 change in the condition from the time of sale. Defendants state that Bextra® was and is safe

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1 and effective when used in accordance with its FDA-approved prescribing information.
2 Defendants state that the potential effects of Bextra® were and are adequately described in its
3 FDA-approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny that Bextra® is defective or
5 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint,
6 including all subparts.

7 99. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny the allegations in this paragraph of the Complaint.

12 100. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
17 allegations in this paragraph of the Complaint.

18 101. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
23 allegations in this paragraph of the Complaint.

24 102. Defendants state that this paragraph of the Complaint contains legal contentions to
25 which no response is required. To the extent that a response is deemed required, Defendants
26 are without knowledge or information sufficient to form a belief as to the truth of the
27 allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.
28 Defendants state that Bextra® was and is safe and effective when used in accordance with its

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1 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
2 were and are adequately described in its FDA-approved prescribing information, which was at
3 all times adequate and comported with applicable standards of care and law. Defendants deny
4 that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
5 paragraph of the Complaint, including all subparts.

6 103. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
8 same. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
13 allegations in this paragraph of the Complaint.

14 104. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
16 same. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph
21 of the Complaint.

22 105. Defendants state that this paragraph of the Complaint contains legal contentions to
23 which no response is deemed required. To the extent a response is deemed required,
24 Defendants deny the allegations in this paragraph of the Complaint.

25 106. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
2 caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the
3 Complaint.

4 107. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
9 allegations in this paragraph of the Complaint.

10 108. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
12 same. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
17 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
19 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
20 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
21 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
22 with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is
23 defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining
24 allegations in this paragraph of the Complaint.

25 109. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 110. Defendants state that this paragraph of the Complaint contains legal contentions to
3 which no response is deemed required. To the extent a response is deemed required,
4 Defendants admit that they had duties as are imposed by law but deny having breached such
5 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 111. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
12 same. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 112. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
19 deny the remaining allegations in this paragraph of the Complaint.

20 113. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 114. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
28 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this

1 paragraph of the Complaint.

2 115. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 116. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 117. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Third Cause of Action: Breach of Express Warranty**

9 118. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 119. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
13 same. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants admit that they provided FDA-approved prescribing information regarding
18 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 120. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
21 same. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants admit that they provided FDA-approved prescribing information regarding
26 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint,
27 including all subparts.

28 121. Defendants deny the allegations in this paragraph of the Complaint.

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1 122. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants admit that they provided FDA-approved prescribing information regarding
6 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 123. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that they provided FDA-approved prescribing information regarding
12 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
13 the Complaint.

14 124. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
16 same. Defendants admit that they provided FDA-approved prescribing information regarding
17 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 125. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 126. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
26 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this
27 paragraph of the Complaint.

28 127. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 129. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Fourth Cause of Action: Breach of Implied Warranty**

7 130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
8 Complaint as if fully set forth herein.

9 131. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
10 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
11 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
12 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
13 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
14 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
15 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 132. Defendants admit that they provided FDA-approved prescribing information regarding
18 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
19 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
20 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
21 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
22 prescribing information. Defendants deny the remaining allegations in this paragraph of the
23 Complaint.

24 133. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
26 same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
27 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
28 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny

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1 the remaining allegations in this paragraph of the Complaint.

2 134. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
4 same. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 135. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
9 same. Defendants state that Bextra® was expected to reach consumers without substantial
10 change in the condition from the time of sale. Defendants deny the remaining allegations in
11 this paragraph of the Complaint.

12 136. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
14 same. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
16 deny the remaining allegations in this paragraph of the Complaint.

17 137. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 138. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
25 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this
26 paragraph of the Complaint.

27 139. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

1 140. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 141. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

6 142. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
7 Complaint as if fully set forth herein.

8 143. Defendants state that this paragraph of the Complaint contains legal contentions to
9 which no response is deemed required. To the extent a response is deemed required,
10 Defendants admit that they had duties as are imposed by law but deny having breached such
11 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 144. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint, including all subparts.

22 145. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 146. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
5 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

6 147. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 148. Defendants deny any wrongful conduct and deny the remaining allegations in this
13 paragraph of the Complaint.

14 149. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
16 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 150. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
20 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
21 paragraph of the Complaint.

22 151. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
24 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
25 paragraph of the Complaint.

26 152. Defendants deny any wrongful conduct and deny the remaining allegations in this
27 paragraph of the Complaint.

28 153. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
2 same. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 154. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 155. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
16 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this
17 paragraph of the Complaint.

18 156. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 157. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 158. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Sixth Cause of Action: Unjust Enrichment**

25 159. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
26 Complaint as if fully set forth herein.

27 160. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

161. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

163. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

164. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,” Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

1 **III.**

2 **GENERAL DENIAL**

3 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'
4 Complaint that have not been previously admitted, denied, or explained.

5 **IV.**

6 **AFFIRMATIVE DEFENSES**

7 Defendants reserve the right to rely upon any of the following or additional defenses to
8 claims asserted by Plaintiffs to the extent that such defenses are supported by information
9 developed through discovery or evidence at trial. Defendants affirmatively show that:

10 **First Defense**

11 1. The Complaint fails to state a claim upon which relief can be granted.

12 **Second Defense**

13 2. Bextra® is a prescription medical product. The federal government has preempted the
14 field of law applicable to the labeling and warning of prescription medical products.
15 Defendants' labeling and warning of Bextra® was at all times in compliance with applicable
16 federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon
17 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
18 and violate the Supremacy Clause of the United States Constitution.

19 **Third Defense**

20 3. At all relevant times, Defendants provided proper warnings, information and
21 instructions for the drug in accordance with generally recognized and prevailing standards in
22 existence at the time.

23 **Fourth Defense**

24 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
25 Bextra® conformed to the generally recognized, reasonably available, and reliable state of
26 knowledge at the time the drug was manufactured, marketed and distributed.

27 **Fifth Defense**

28 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

2 **Sixth Defense**

3 6. Plaintiffs' action is barred by the statute of repose.

4 **Seventh Defense**

5 7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were
6 contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and
7 any recovery by Plaintiffs should be diminished accordingly.

8 **Eighth Defense**

9 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
10 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
11 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
12 liable in any way.

13 **Ninth Defense**

14 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
15 intervening causes for which Defendants cannot be liable.

16 **Tenth Defense**

17 10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were
18 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
19 of God.

20 **Eleventh Defense**

21 11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs .

22 **Twelfth Defense**

23 12. A manufacturer has no duty to warn patients or the general public of any risk,
24 contraindication, or adverse effect associated with the use of a prescription medical product.
25 Rather, the law requires that all such warnings and appropriate information be given to the
26 prescribing physician and the medical profession, which act as a "learned intermediary" in
27 determining the use of the product. Bextra® is a prescription medical product, available only
28 on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs'

1 treating and prescribing physicians.

2 **Thirteenth Defense**

3 13. The product at issue was not in a defective condition or unreasonably dangerous at the
4 time it left the control of the manufacturer or seller.

5 **Fourteenth Defense**

6 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
7 for its intended use and the warnings and instructions accompanying Bextra® at the time of the
8 occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

9 **Fifteenth Defense**

10 15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the
11 Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable
12 standard of care.

13 **Sixteenth Defense**

14 16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of
15 the product Bextra® after the product left the control of Defendants and any liability of
16 Defendants is therefore barred.

17 **Seventeenth Defense**

18 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of
19 Defendants.

20 **Eighteenth Defense**

21 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent
22 conditions unrelated to Bextra®.

23 **Nineteenth Defense**

24 19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore,
25 the doctrine of assumption of the risk bars or diminishes any recovery.

26 **Twentieth Defense**

27 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
28 preempted in accordance with the Supremacy Clause of the United States Constitution and by

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1 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

2 **Twenty-first Defense**

3 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
4 the subject pharmaceutical product at issue was subject to and received pre-market approval by
5 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

6 **Twenty-second Defense**

7 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
8 Plaintiffs' Complaint was at all times in compliance with all federal regulations and statutes,
9 and Plaintiffs' causes of action are preempted.

10 **Twenty-third Defense**

11 23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary
12 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
13 issue under applicable federal laws, regulations, and rules.

14 **Twenty-fourth Defense**

15 24. Plaintiffs' claims are barred in whole or in part because there is no private right of
16 action concerning matters regulated by the Food and Drug Administration under applicable
17 federal laws, regulations, and rules.

18 **Twenty-fifth Defense**

19 25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate
20 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
21 of Comment j to Section 402A of the Restatement (Second) of Torts.

22 **Twenty-sixth Defense**

23 26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim
24 because Bextra® is a prescription pharmaceutical drug and falls within the ambit of
25 Restatement (Second) of Torts § 402A, Comment k.

26 **Twenty-seventh Defense**

27 27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical
28 product at issue "provides net benefits for a class of patients" within the meaning of Comment f

1 to § 6 of the Restatement (Third) of Torts: Products Liability.

2 **Twenty-eighth Defense**

3 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
4 Products Liability.

5 **Twenty-ninth Defense**

6 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead
7 facts sufficient under the law to justify an award of punitive damages.

8 **Thirtieth Defense**

9 30. Defendants affirmatively aver that the imposition of punitive damages in this case
10 would violate Defendants' rights to procedural due process under the Fourteenth Amendment of
11 the United States Constitution and the Constitutions of the States of South Carolina, Florida,
12 Arkansas, Mississippi, and California, and would additionally violate Defendants' rights to
13 substantive due process under the Fourteenth Amendment of the United States Constitution.

14 **Thirty-first Defense**

15 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
16 Fourteenth Amendments to the United States Constitution.

17 **Thirty-second Defense**

18 32. The imposition of punitive damages in this case would violate the First Amendment to
19 the United States Constitution.

20 **Thirty-third Defense**

21 33. Plaintiffs' punitive damage claims are preempted by federal law.

22 **Thirty-fourth Defense**

23 34. In the event that reliance was placed upon Defendants' nonconformance to an express
24 representation, this action is barred as there was no reliance upon representations, if any, of
25 Defendants.

26 **Thirty-fifth Defense**

27 35. Plaintiffs failed to provide Defendants with timely notice of any alleged
28 nonconformance to any express representation.

1 **Thirty-sixth Defense**

2 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without
3 proof of causation, the claims violate Defendants' rights under the United States Constitution.

4 **Thirty-seventh Defense**

5 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and
6 labeling with respect to the subject pharmaceutical products were not false or misleading and,
7 therefore, constitute protected commercial speech under the applicable provisions of the United
8 States Constitution.

9 **Thirty-eighth Defense**

10 38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly
11 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
12 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
13 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
14 Amendment of the United States Constitution, the Commerce Clause of the United States
15 Constitution, and the Full Faith and Credit Clause of the United States Constitution, and
16 applicable provisions of the Constitutions of the States of South Carolina, Florida, Arkansas,
17 Mississippi, and California. Any law, statute, or other authority purporting to permit the
18 recovery of punitive damages in this case is unconstitutional, facially and as applied, to the
19 extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and
20 restrain the jury's discretion in determining whether to award punitive damages and/or the
21 amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as
22 to what conduct will result in punitive damages; (3) permits recovery of punitive damages
23 based on out-of-state conduct, conduct that complied with applicable law, or conduct that was
24 not directed, or did not proximately cause harm, to Plaintiffs ; (4) permits recovery of punitive
25 damages in an amount that is not both reasonable and proportionate to the amount of harm, if
26 any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury
27 consideration of net worth or other financial information relating to Defendants; (6) lacks
28 constitutionally sufficient standards to be applied by the trial court in post-verdict review of any

1 punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of
2 punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including,
3 without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production*
4 *Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*,
5 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
8 and marketing of Bextra®, if any, used in this case, included adequate warnings and
9 instructions with respect to the product's use in the package insert and other literature, and
10 conformed to the generally recognized, reasonably available, and reliable state of the
11 knowledge at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,
14 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
15 the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon
18 information and belief, such injuries and losses were caused by the actions of persons not
19 having real or apparent authority to take said actions on behalf of Defendants and over whom
20 Defendants had no control and for whom Defendants may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,
27 waiver, and/or estoppel.

28

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Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of

1 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if
2 any, are determined. Defendants seek an adjudication of the percentage of fault of the
3 claimants and each and every other person whose fault could have contributed to the alleged
4 injuries and damages, if any, of Plaintiffs .

5 **Fifty-second Defense**

6 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the
7 common law gives deference to discretionary actions by the United States Food and Drug
8 Administration under the Federal Food, Drug, and Cosmetic Act.

9 **Fifty-third Defense**

10 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
11 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
12 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'
13 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
14 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
15 and with the specific determinations by FDA specifying the language that should be used in the
16 labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the
17 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
18 United States.

19 **Fifty-fourth Defense**

20 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity
21 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

22 **Fifty-fifth Defense**

23 55. Defendants state on information and belief that the Complaint and each purported cause
24 of action contained therein is barred by the statutes of limitations contained in California Code
25 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
26 as may apply.

27 **Fifty-sixth Defense**

28 56. Defendants state on information and belief that any injuries, losses, or damages suffered

1 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other
2 actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery
3 against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

4 **Fifty-seventh Defense**

5 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
6 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
7 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
8 damages is also barred under California Civil Code § 3294(b).

9 **Fifty-eighth Defense**

10 58. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by
11 Rule 1.120 of the Florida Rules of Civil Procedure.

12 **Fifty-ninth Defense**

13 59. Plaintiffs' claims are barred because Bextra® was designed, manufactured, and
14 marketed in accordance with the state of the art at the time of manufacture per § 768.1257,
15 Florida Statutes.

16 **Sixtieth Defense**

17 60. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable
18 because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiff
19 and Decedent, Defendants had complied with applicable regulations of the federal Food & Drug
20 Administration and are entitled to application of § 768.1256, Florida Statutes.

21 **Sixty-first Defense**

22 61. Plaintiffs' and Decedent's injuries and damages, if any, were proximately caused by the
23 negligence or fault of Plaintiffs and Decedent, or persons or parties whose identities are
24 unknown at this time, and such comparative negligence or fault is sufficient to proportionately
25 reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have its liability to the
26 Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities,
27 pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted
28 in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on

1 the basis of Defendants' percentage of fault, taking into account the percentage of fault
2 attributable to all other persons, whether or not a party hereto, and not on the basis of joint and
3 several liability. The persons or entities referred to in this paragraph that are presently
4 unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells*
5 *Fargo*, 678 So. 2d 1262 (Fla. 1996).

6 **Sixty-second Defense**

7 62. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade
8 Practices Act ("FDUTPA").

9 **Sixty-third Defense**

10 63. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs'
11 FDUTPA claim is improper and should be dismissed.

12 **Sixty-fourth Defense**

13 64. The acts or practices of which Plaintiffs complain were and are required or specifically
14 permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a
15 claim, and should be dismissed with prejudice.

16 **Sixty-fifth Defense**

17 65. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with
18 regard to Plaintiffs or Decedent or otherwise.

19 **Sixty-sixth Defense**

20 66. Plaintiffs' claims are barred, in whole or in part, pursuant to South Carolina Code Ann.
21 § 15-3-20.

22 **Sixty-seventh Defense**

23 67. Plaintiffs' fraud based claims, if any, are not stated with particularity as required by
24 Rule 9 of the Arkansas Rules of Civil Procedure.

25 **Sixty-eighth Defense**

26 68. Plaintiffs' damages, if any, must be reduced by the percentage of fault attributable to
27 Plaintiffs and Decedent and to nonparties as provided by Ark. Code Ann. § 16-55-202.

28

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Sixty-ninth Defense

69. Plaintiffs' claims are barred and/or limited by the provisions of the Arkansas Products Liability Act, Ark. Code Ann. § 16-116-101, et seq.

Seventieth Defense

70. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Arkansas Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201, et seq.

Seventy-first Defense

71. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs' claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiffs and Decedent failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

Seventy-second Defense

72. Any verdict or judgment rendered against Defendant must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs and Decedent may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs or Decedent and any such parties.

Seventy-third Defense

73. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Seventy-fourth Defense

74. Defendant asserts that Plaintiffs' claim for punitive damages is governed and limited by

1 Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the
2 same.

3 **Seventy-fifth Defense**

4 75. Bextra® and the Defendants' actions conformed to the state of the art medical and
5 scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable
6 product safety statutes and regulations as described in Restatement (Third) of Torts: Products
7 Liability § 4.

8 **Seventy-sixth Defense**

9 76. Defendants satisfied their duty to warn under the learned intermediary doctrine and
10 Plaintiffs' claims are therefore barred.

11 **Seventy-seventh Defense**

12 77. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and
13 hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

14 **Seventy-eighth Defense**

15 78. Plaintiffs failed to join all indispensable parties; as a result of such failure to join,
16 complete relief cannot be accorded to those already parties to the action and will result in
17 prejudice to Defendant in any possible future litigation.

18 **Seventy-ninth Defense**

19 79. Any judicially-created definitions of manufacturing defect and design defect, and
20 standards for determining whether there has been an actionable failure to ward, are
21 unconstitutional in that, among other things, they are void for vagueness and undue burden on
22 interstate commerce, as well as an impermissible effort to regulate in an area that previously has
23 been preempted by the federal government.

24 **Eightieth Defense**

25 80. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
26 Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any
27 award of punitive damages is barred.

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Eighty-first Defense

81. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

Eighty-second Defense

82. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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March 26, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

March 26, 2008

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